

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BTL INDUSTRIES, INC., )  
Plaintiff, )  
v. ) C.A. No. 20-239-CFC  
ALLERGAN PLC, ALLERGAN, )  
INC., and ZELTIQ AESTHETICS, )  
INC., )  
Defendants. )

**REPLY BRIEF IN SUPPORT OF BTL'S  
MOTION TO DISMISS ZELTIQ'S AMENDED COUNTERCLAIMS**

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To survive BTL’s motion to dismiss, Zeltiq needs to persuade the Court that the message “Super Bowl Champion Rob Gronkowski loves Emsculpt!” conveys to reasonable consumers that, with only a few Emsculpt treatments, “they too can play football like top NFL draft picks.” Am. Counterclaims ¶¶49-50. This and the many other unsupported allegations and implausible inferences that plague Zeltiq’s counterclaims justify dismissal. Courts are “not compelled to accept unwarranted inferences, unsupported conclusions or legal conclusions disguised as factual allegations.” *Baraka v. McGreevey*, 481 F.3d 187, 211 (3d Cir. 2007).

Furthermore, while statements that are literally false are presumed to be deceptive, statements that are merely misleading do not benefit from that presumption, so Zeltiq’s counterclaims must plead sufficient facts to support a plausible inference of deception as well as materiality and harm. *See Pernod Ricard USA, LLC v. Bacardi U.S.A., Inc.*, 653 F.3d 241, 248 (3d Cir. 2011). By barely mentioning deception, materiality, and harm in its opposition papers, however, Zeltiq effectively concedes its failure to allege these elements. The Court should grant BTL’s motion to dismiss.

**I. Zeltiq fails to state a claim regarding a correlation between technical characteristics and efficacy.**

**A. Zeltiq improperly relies on non-actionable statements.**

Unlike BTL’s complaint against the Defendants, which focuses on a *specific* advertising campaign by Defendants that boasts falsely about the CoolTone

product delivering 50% greater magnetic intensity than the Emsculpt device, Zeltiq's counterclaims point to no specific factual inaccuracy. Instead, Zeltiq's retaliatory counterclaims stitch together unrelated statements from different sources to suggest that BTL is misleading consumers as well, but Zeltiq's allegations do not withstand scrutiny. As BTL has argued, many statements are categorically non-actionable either because Zeltiq does not allege any facts making it plausible that statements made outside the United States have a substantial effect on U.S. commerce (¶¶24-25) or because Zeltiq does not allege that the particular statements are false or misleading (¶¶29-30). Having ignored these arguments, Zeltiq waived any objection to dismissal of the claims that rely on these non-actionable statements. *See Dreibelbis v. Scholton*, 274 F. App'x 183, 185 (3d Cir. 2008) (failure to make an argument in response to a motion to dismiss waives the argument).

**B. Zeltiq fails to adequately plead deception, materiality, and harm.**

Because the challenged statements could be, at most, merely misleading and not literally false, Zeltiq needs to plead facts making a plausible case for the additional elements of (i) deception; (ii) materiality; and (iii) harm. *Pernod*, 653 F.3d at 248. Zeltiq's counterclaims are deficient on all three points.

**1. No deception**

Zeltiq asserts (at 17) that it "bears no burden" to plead deception because

this element is presumed. But Zeltiq gets the law wrong: that presumption applies only to plausible claims of literally falsity, which Zeltiq does not assert. *Pernod*, 653 F.3d at 248. Zeltiq does not—and cannot—question the accuracy of the technical specifications in ¶¶24-30.

As a fallback position, Zeltiq argues (at 18) that it has pleaded “general allegations of deception.” But conclusory allegations that statements were “deceptive” will not do; Zeltiq must plead *facts* in support of a plausible inference that consumers have been, or are likely to be, deceived. *See Accenture Glob. Servs. GMBH v. Guidewire Software Inc.*, 581 F. Supp. 2d 654, 667 (D. Del. 2008) (dismissing false advertising claim for failing “to allege facts suggesting that the marketplace was actually confused or misled”). Nor is it enough to allege generally that consumers have been deceived by BTL; rather, Zeltiq needs to link the deception to the specific statements. *See Nespresso USA, Inc. v. Ethical Coffee Co. SA*, No. 16-cv-194-GMS, 2017 WL 3021066, at \*4 (D. Del. July 14, 2017) (refusing “to create the entire causal chain linking . . . injuries to consumer confusion based” largely on “attorney argument”). This Zeltiq has not done.

This is particularly true, as here, where there are sophisticated consumers. Zeltiq fails to address the fact that, by law, only medical professionals may purchase either the CoolTone product or the Emsculpt device. While Zeltiq asserts (at 19) that the advertising might be read by patients, the medical “context [is

highly] important in discerning the message conveyed,” *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 229 (3d Cir. 1990), because doctors are knowledgeable consumers who are not easily misled. It is inappropriate to use patients for a false advertisement claim when they cannot actually purchase the product that is the subject of the advertisement.

**2. No materiality.**

Zeltiq suggests (at 19-20) that the statements in ¶¶24-60 are material because they supposedly “relate to the effectiveness of [the] Emsculpt” device. But not every challenged statement about the Emsculpt device relates to its effectiveness. And not every statement relating to effectiveness is material. Zeltiq’s reliance on *10x Genomics, Inc. v. Celsee, Inc.*, No. 19-cv-862-CFC-SRF, 2019 WL 5595666, at \*6 (D. Del. Oct. 30, 2019), is misplaced. There, the court found materiality where the complaint pleaded facts plausibly suggesting that: (1) the cited technical specifications were a key performance metric; (2) customers inferred from the statements that one competitor’s device was more efficacious than the other’s; and (3) that inference was likely to influence purchasing decisions. *Id.* No corresponding facts are found in Zeltiq’s counterclaims.

**3. No harm.**

Zeltiq asserts (at 20-21) that harm and nexus as to every statement in ¶¶24-60 may be presumed because Zeltiq and BTL are competitors. For any such

presumption to apply, however, the challenged statement needs to compare one competing product to another. *See Ortho Pharm. Corp. v. Cosprophar, Inc.*, 32 F.3d 690, 696 (2d Cir. 1994) (presumption of harm does not attach where the “advertisements make no direct reference to any competitor’s products”); *see also Healthpoint, Ltd. v. Stratus Pharm., Inc.*, 273 F. Supp. 2d 871, 885 (W.D. Tex. 2001) (“[W]hen the defendant has falsely advertised its product but made no comparison with a competitor’s product, the courts have refused to apply the presumption of causation and harm, even when the products were in obvious competition. This is so because the courts want to prevent a windfall for plaintiff from speculative damages.”). Further, where there is a product comparison, the presumption will apply only where there are facts showing deceptive intent. *See Merck Eprova AG v. Gnosis S.p.A.*, 760 F.3d 247, 260-61 (2d Cir. 2014) (“deliberate deception” is prerequisite to presumption of harm).

Zeltiq identifies only one statement (in ¶28)—allegedly posted by an area sales manager on what appears to be a dormant Instagram account—comparing the Emsculpt device against a “competitor,” allegedly the CoolTone product. However, Zeltiq does not allege facts showing deceptive intent. Nor is it plausible that this single post, published months ago by a low-level employee, misled doctors into “believing that Emsculpt is clinically proven to be more effective than CoolTone,” (¶28), or that this post influenced purchasing decisions, or that it

proximately harmed Zeltiq. *See Pizza Hut, Inc. v. Papa John's Int'l, Inc.*, 227 F.3d 489, 503 (5th Cir. 2000).

**C. The statements are puffery.**

Notwithstanding Zeltiq's protestations to the contrary, “[d]istrict courts often resolve whether a statement is puffery” at the pleading stage. *Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv. Inc.*, 911 F.2d 242, 245 (9th Cir. 1990). Zeltiq argues that the statements in ¶¶24-30 cannot be puffery because they suggest “improved results are linked to . . . quantified improvements to technical specifications.” Opp. 11. But there is no such linkage between the puffery and the quantification; Zeltiq points to unrelated advertisements to make its argument. The quantitative statements to which Zeltiq points—i.e., “4x Larger Spot Size” and “270% More Energy” (the accuracy of which Zeltiq does not challenge) (¶¶27-28)—appeared in separate social media posts *without* any claim of better results. And the puffery about “better and faster results” (¶24)—was posted on a different social media account months later and *without* describing any quantified improvements to technical specifications. *See Pizza Hut*, 227 F.3d at 499 (“Better Ingredients. Better Pizza.” standing alone is non-actionable puffery.”).

**II. Zeltiq fails to state a claim concerning fat reduction.**

Zeltiq makes no response to BTL's argument that third-party statements (at ¶¶37-38) are non-actionable because they cannot be attributed to BTL. Claims

based on those statement should be dismissed.

Zeltiq's other arguments in defense of the claims in ¶¶31-47 all lack merit.

**A. The statements are not “establishment claims.”**

Zeltiq (at 11-12) incorrectly describes the statements in ¶¶31-41 concerning the fat-reducing capabilities of the Emsculpt device as “establishment” claims—i.e., statements that “tests or studies prove a product superior.” *See CareDx, Inc. v. Natera, Inc.*, No. 19-cv-662-CFC-CJB, 2019 WL 7037799, at \*8 (D. Del. Dec. 20, 2019). But none of the statements represent—explicitly or implicitly—that *studies prove* the Emsculpt device superior to any product.

Even if the statements were about particular studies comparing products, Zeltiq would still fail to state a claim. For example, *CareDx, Inc. v. Natera, Inc.*, No. 19-cv-662-CFC, 2020 WL 401773 (D. Del. Jan. 24, 2020) and *Federal Express Corp. v. UPS, Inc.*, 765 F. Supp. 2d 1011, 1020 (W.D. Tenn. 2010) relied on factual allegations supporting a plausible inference that the pertinent studies *deviated from acceptable scientific standards*. Zeltiq makes no such assertion.

Although Zeltiq criticizes four studies testing the Emsculpt device's efficacy for fat reduction, Zeltiq does not plausibly allege that the studies are unreliable. Indeed, apart from the weak criticism that one study was done on animals rather than humans, Zeltiq pleads no actual *facts* pertinent to the studies' scientific merit. Zeltiq's conclusory opinion that these studies are unpersuasive is not entitled to

any weight.

Finally, because the Emsculpt device has obtained regulatory clearance in other countries for fat reduction, statements about fat reduction directed to consumers in those countries are entirely appropriate. Mot. 14.

**B. Zeltiq’s false-by-necessary-implication claim is implausible.**

A statement is literally-false-by-necessary-implication only if the “consumer will unavoidably receive a false message.” *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578, 587-88 (3d Cir. 2002). Zeltiq’s allegations fall short of pleading unavoidability. Zeltiq argues that a lone Facebook post (¶33) stating that “Both [the EMSCULPT and CoolSculpting] devices are FDA cleared devices” unavoidably conveys the impression that the Emsculpt device is “FDA-cleared for fat reduction.” Opp. 14. Not only might doctors draw other conclusions based on that passage, but it is implausible that they would make the logical leap that Zeltiq suggests. *See Fed. Exp.*, 765 F. Supp. 2d at 1022 (“A ‘false-by-necessary-implication claim fails if the statement can reasonably be understood to convey different messages.’”) (citation omitted).

Zeltiq’s argument relies on the reader having independent personal knowledge that the CoolSculpting product “is Zeltiq’s fat-reduction product.” Opp. 14. But “[t]he greater the degree to which a message relies upon the viewer or consumer to integrate its components and draw the apparent conclusion, … the

less likely it is that a finding of literal falsity will be supported.” *Novartis*, 290 F.3d at 587. Moreover, anyone who wondered about the Emsculpt device’s clearances could easily find it on BTL’s website (or the FDA’s). Furthermore, the challenged post says that the Emsculpt device “increas[es] muscle mass,” while “CoolSculpting does not,” (¶ 33), indicating that the devices do not work in the same way and so may not have the same FDA clearances. *See Pharmacia Corp. v. GlaxoSmithKline Consumer Healthcare, L.P.*, 292 F. Supp. 2d 594, 600 (D.N.J. 2003) (rejecting claim where the alleged necessary implication was “open to interpretation”).

**C. Zeltiq fails to adequately plead a misleading-statement theory.**

Zeltiq argues in the alternative (at 14) that the Facebook post (at ¶33) misleads doctors into believing that the Emsculpt device is “FDA-cleared for fat reduction” because “BTL has mixed and matched references to FDA-approved and unapproved uses.” But that is the sum total of Zeltiq’s argument; it pleads no facts plausibly suggesting that anyone was deceived by the supposed mixing and matching, that the message was material to purchasing decisions by medical professionals, or that it caused Zeltiq any harm.

Zeltiq’s allegation (at 14) that similar mixing-and-matching on BTL’s webpage misled readers about the FDA clearances for the Emsculpt device is even more far-fetched since the webpage recites the actual FDA clearances. Zeltiq

complains (at 14) that this language is “small” and “at the very bottom of the webpage.” But a similar disclaimer appears on Zeltiq’s own webpage, indicating that the position of such disclaimers is the normal course of trade.

### **III. Zeltiq’s claims concerning athletic benefits are implausible.**

With regard to the statement that treatments using the Emsculpt device qualify as a form of “core conditioning” (¶¶42-43), Zeltiq simply ignores BTL’s arguments that this statement is factually consistent with its FDA clearance and that Zeltiq’s argument to the contrary is predicated upon an idiosyncratic and unsubstantiated definition of “core conditioning,” which Zeltiq believes must involve the “use [of your] abdominal and back muscles in a coordinated fashion.” Mot. 17-18; Opp. 15.

Zeltiq’s remaining arguments are likewise unpersuasive. Zeltiq argues that two statements summarizing peer-reviewed studies “unambiguously” convey to consumers that the Emsculpt device prevents dementia and cardiovascular disease. Am. Counterclaims ¶48; Opp. 4. But the statements do not actually say—and no doctor would seriously conclude—that toning one’s calves prevents dementia or that toning one’s buttocks prevents heart disease. Zeltiq’s argument assumes that there is no room for puffery in the aesthetic body-shaping industry—a premise for which Zeltiq notably cites no authority. Next, while Zeltiq acknowledges that “no reasonable person would accept as true claims that an energy drink allowed a

consumer to master origami while beating [a] hacky sack record,” (Opp. 16), Zeltiq nevertheless insists that reasonable people would conclude from celebrity endorsements “that with a few Emsculpt treatments, they too can play football like top NFL draft picks, fight like a heavyweight champion and/or play soccer like” a top-division pro. Am. Counterclaims ¶¶49-50. Zeltiq’s allegations are absurd on their face—and, unsurprisingly, unsupported by any facts. The statements are also unlikely to mislead doctors because they were made in the context of a lighthearted competition among sales reps kept at home due to COVID-19. Opp. 16-17. *Cf. Pernod*, 653 F.3d at 253 (courts must review statements in context).

And, yet again, Zeltiq fails adequately to plead deception, materiality, and harm. *See Pizza Hut*, 227 F.3d at 503-04.

#### **IV. Zeltiq fails to adequately plead treble damages.**

Zeltiq is not entitled to treble damages because no alleged facts support the inference that BTL knowingly and willfully made false statements, which is what Zeltiq concedes is the pertinent inquiry. Opp. 21. *See Spotless Enters., Inc. v. Carlisle Plastics, Inc.*, 56 F. Supp. 2d 274, 287 (E.D.N.Y. 1999). Moreover, the Lanham Act “makes an award of actual damages a prerequisite of any award of treble damages.” *ACCU Pers., Inc. v. AccuStaff, Inc.*, 846 F. Supp. 1191, 1216 (D. Del. 1994). Because Zeltiq has failed to adequately plead harm, it does not qualify for treble damages.

**V. Conclusion.**

BTL's motion to dismiss should be granted. Because Zeltiq has already unsuccessfully amended its claims, dismissal with prejudice is warranted.

Respectfully submitted,

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Dated: August 10, 2020

## CERTIFICATE OF COMPLIANCE

Pursuant to the Court's November 6, 2019 Standing Order, I hereby confirm that this brief complies with the type and number limitations set forth in the Standing Order. I certify that this document contains 2495 words, which were counted using the word count feature in Microsoft Word, in 14-point Times New Roman font. The word count does not include the cover page, table of contents and authorities, or the counsel blocks.

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